

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

SCALING UP ANTIRETROVIRAL THERAPY: EXPERIENCE IN UGANDA

CASE STUDY



World Health Organization



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CASE STUDY

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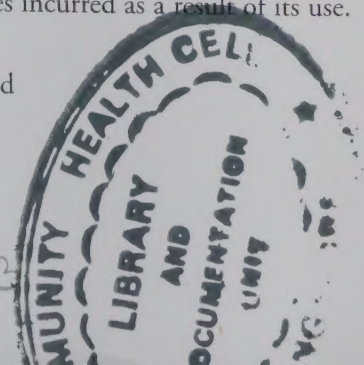
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About This Series

With 42 million people now living with HIV/AIDS, expanding access to antiretroviral treatment for those who urgently need it is one of the most pressing challenges in international health. Providing treatment is essential to alleviate suffering and to mitigate the devastating impact of the epidemic. It also presents unprecedented opportunities for a more effective response by involving people living with HIV/AIDS, their families and communities in care and will strengthen HIV prevention by increasing awareness, creating a demand for testing and counselling and reducing stigma and discrimination.

The challenges are great. Sustainable financing is essential. Drug procurement and regulatory mechanisms must be established and strengthened. Health care workers must be trained, infrastructure improved, communities educated and diverse stakeholders mobilized to play their part. This series, *Perspectives and Practice in Antiretroviral Treatment*, provides examples of how such challenges are being overcome in the growing number of developing countries in which antiretroviral treatment programmes are underway. The case studies and analyses in this series show how governments, civil society organizations, private corporations and others are successfully providing antiretroviral treatment and care to people with HIV/AIDS, even in the most resource-constrained settings. In documenting these pioneering programmes, WHO hopes that their experiences will both inform and inspire everyone who is working to make access to treatment a reality.

Background

Uganda was one of the first African countries to respond aggressively to the HIV/AIDS epidemic, moving rapidly to institute measures aimed at preventing HIV transmission. HIV prevalence rates once described as being among the highest in Africa and tending toward 30% have declined to under 10% within the last two decades. Although there is evidence of a decline in new infections, the number of people already infected and progressing to AIDS is increasing. At the end of 2002, WHO estimated that 600 000 people were living with HIV infection in Uganda, of which between 60 000 and 90 000 would need access to antiretroviral (ARV) therapy on clinical grounds because of advanced HIV infection.

To add to its already comprehensive response, the Uganda government embarked on an effort to provide access to antiretroviral therapy, in collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS). The UNAIDS HIV Drug Access Initiative was launched in 1997. The purpose of the Drug Access Initiative was to induce relevant changes in the health care system to improve access to HIV/AIDS care, including access to ARV therapy. By the end of 2000, the Drug Access Initiative had resulted in about 1000 clients on ARV therapy¹.

As of April 2000, the Ministry of Health assumed sole responsibility for managing access to ARV therapy. An expansion plan to increase access to ARV therapy was developed with support from WHO – the National Strategic Framework for Expansion of HIV/AIDS Care and Support in Uganda from 2001/2002 to 2005/2006². This expansion plan is part of a multi-year scale-up that is to be implemented within the framework of the National Health Policy and the HIV/AIDS Health Sector Strategic Plan.

The main objective of the Framework is to build capacity for the expansion and acceleration of access to comprehensive HIV/AIDS care. It emphasizes the need for the implementation of care across a continuum and provides a coordinated and standardized approach to delivery.

In the first phase, the Framework aimed to increase the number of treatment centres from five in Kampala (the capital) to include an additional three centres in district hospitals outside Kampala.

The National Advisory Board

In accordance with the terms of an agreement signed with UNAIDS, the Drug Access Initiative set up a National Advisory Board in the Ministry of Health to direct the intro-

duction of ARV therapy and to roll out a more comprehensive approach to the medical management of people with HIV/AIDS. The 15-member Board included representatives from the Ministries of Health, Finance, Planning & Economic Development, Defence and Gender, Labour & Social Development; the Manager of the National AIDS Control Programme (Ministry of Health); representatives from the Uganda AIDS Commission; representatives from nongovernmental organizations such as the AIDS Support Organization (TASO); public health specialists; clinicians with experience in the clinical management of HIV infection; and representatives of people living with HIV/AIDS.

The functions of the National Advisory Board were:

- ▶ to make recommendations to the government on HIV-related drug policy such as currently available therapies, clinical management of HIV infection and the establishment of a list of HIV-related drugs relevant to the local context;
- ▶ to estimate the country's needs for HIV-related drugs;
- ▶ to recommend a policy for the public health sector in relation to the rational prescription, distribution and use of HIV-related drugs, as well as advising on regulations for privately funded purchases;
- ▶ to recommend objective criteria for the profile of people who may participate in the Initiative; and
- ▶ to suggest an action plan for the improvement of health care infrastructure, where necessary, to make ARV therapy more widely accessible in the country.

Three subcommittees were formed to carry out the various functions; Drug Policy and Financing; Vertical Transmission; and Care and Practice.

The Subcommittee on Drug Policy developed guidelines that limited the price mark-ups on ARV drugs at different levels of the drug distribution chain; it outlined a document on alternative sources of financing and potential funders and determined selection criteria for ARV therapy as well as criteria for the accreditation of treatment centres.

The Subcommittee on Vertical Transmission defined the policy document on the prevention of mother-to-child transmission of HIV in Uganda and developed training guidelines for health workers.

The Subcommittee on Care and Practice developed a standardized medical record form for use in treatment centres, guidelines for ARV therapy and the management of opportunistic infections and information, education and communication materials.

This consultative structure was maintained and integrated into the Ministry of Health after the Drug Access Initiative

ended in 2000. The Ministry of Health reorganized the membership and named it a task force for the expansion of comprehensive HIV care whose major task was to develop a strategy for scaling up ARV therapy. Upon completion of their assigned task, the team was expanded and assigned a new role as a National Committee on Access to ARV Therapy (Box 1).

Box 1. The National Committee on Access to ARV Therapy

In its efforts to scale-up access to ARV agents in Uganda, the Ministry of Health appointed a National Committee on Access to ARV Therapy with 24 members to oversee ARV therapy. The Committee is multidisciplinary, and its members have initially been appointed for 2 years. It has representatives from United Nations agencies, bilateral agencies, people living with HIV/AIDS, nongovernmental and community-based organizations, faith-based organizations, the Ministry of Health and leading physicians in HIV/AIDS care both in government and private health facilities. The Committee can co-opt other members as it deems appropriate.

The Committee’s tasks included:

- developing a policy document for ARV therapy in Uganda;
- overseeing the development of technical guidelines for ARV therapy;
- quantifying the logistical needs for implementing the ARV therapy programme; and
- monitoring and evaluating the ARV therapy programme.

To carry out its duties more efficiently, the ARV therapy committee formed five subcommittees covering policy, logistics, finance, clinical care & practice and advocacy. The subcommittees hold two working meetings per month, whereas the Committee meets once a month to update all members on the progress of the subcommittees and to build consensus on issues decided by the subcommittees.

The Committee produced working drafts of the following documents within 5 months.

- *National policy for ARV therapy in Uganda*
- *National ARV treatment and care guidelines for adults and children*
- *Implementation guidelines for ARV therapy in Uganda*
- *National training guidelines on ARV therapy in Uganda*
- *Costing of the national ARV therapy programme (including different scenarios of ARV therapy provision)*
- *Quantification of ARVs for public sector health facilities*
- *Strategy for ARV therapy advocacy in Uganda*

The clinical care guidelines have been pretested in two centres providing ARV therapy services, to assess the ease and feasibility of using them. They have been revised based on the findings. The building of consensus on the major policy issues has been enhanced by the multidisciplinary composition of the Committee and holding several stakeholders’ workshops where other people are invited to share their views freely. Appropriate changes have been incorporated into the documents.

Building consensus on some critical issues has been difficult, such as the criteria for deciding who can access free ARV agents in the public sector. The Committee has made recommendations on such issues. The higher authorities in the government will make the final decisions.

ARV therapy regimens

Drug Access Initiative (1997–2000)

When the Drug Access Initiative started in 1998, the National Advisory Board developed ARV therapy guidelines in which two different treatment approaches were proposed. The first approach targeted total suppression of viral replication and foresaw the use of three-drug combination therapy regimens, including two nucleoside reverse transcriptase inhibitors and either a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor. The second approach aimed for partial viral suppression only and foresaw the use of two nucleoside reverse transcriptase inhibitors, and hydroxyurea could be added to the regimen. In 1998, partly suppressive ARV therapy was felt to be justified in Uganda given that many people could not afford triple therapy, and because it has been demonstrated that partial viral suppression is better than none at all.

Given this evolution and the WHO recommendations on scaling up access to ARV therapy published in June 2002, the National Advisory Board is currently revising its ARV therapy guidelines. The ninth draft of clinical guidelines was released for review in March 2003⁵. It contains recommendations on voluntary counselling and testing, laboratory diagnosis and assessment of HIV clinical evaluation and when to start ARV therapy. Dual therapy is no longer recommended, and first- and second-line regimens are proposed (Table 2).

The first-line regimens are recommended at the national level to cover most people needing therapy in Uganda. The guideline recommends the use of a non-nucleoside as the third drug in first-line regimens, because it is less expensive, preserves the

Table 1. ARV regimens in Uganda, 2000 and 2002

	Drug Access Initiative (end 2000)*	Expansion phase (end of 2002)**
Monotherapy	2%	
Dual therapy regimens	47%	
Triple therapy regimens	51%	100%
% with a non-nucleoside	-	70%
% with a protease inhibitor	-	30%

Sources: * P. Weidle et al³; ** Report on a rapid assessment of access to antiretroviral therapy in Uganda⁴

Expansion phase (2002 to the present)

Although the 1998 guidelines on ARV therapy developed by the National Advisory Board remain in effect at the time of writing, the pattern of ARV drug prescription changed significantly in Uganda from 2000 to 2002. As a result of the very significant decreases in the cost of ARV drugs since October 2000, more and more people now receive triple ARV therapy (Table 1).

Table 2. Recommended first- and second-line ARV therapy regimens for adults and adolescents in Uganda

First line regimen	Second line regimen
Zidovudine/lamivudine + efavirenz (or nevirapine)	Stavudine/didanosine + lopinavir with ritonavir boost
Stavudine/lamivudine + nevirapine	Zidovudine/didanosine + lopinavir with ritonavir boost

Source: National ARV treatment and care guidelines for adults and children. Draft 9⁵.

option of using a protease inhibitor at a later date, ensures safety during pregnancy and allows simultaneous treatment of HIV-infected people that have tuberculosis with rifampicin.

For economic reasons and simplicity of administration, only lopinavir with ritonavir boost is recommended as the protease inhibitor for second-line regimens in case of treatment failure. However, other protease inhibitors may be substituted in case this is unavailable. The guidelines also include first-line regimens for infants and children as well as special groups (women of childbearing age and people confirmed as being co-infected with tuberculosis or other opportunistic infections).

Human resources

Uganda lacks adequate numbers of skilled health care personnel as is the case in other countries in sub-Saharan Africa, with only 1600 physicians for a population of over 20 million people.

To support the rational use of the new therapies introduced in the country, the Drug Access Initiative team and the training team of the National AIDS Control Programme combined their human and financial resources in a countrywide training plan for health workers. The training focused on ARV therapy and the use of sophisticated drugs for opportunistic infections at the referral and district levels but also included sessions on drug logistics and stock management. The format was workshops of 1–2 days conducted by Ugandan clinicians and community workers in Kampala. By 2000, the Ministry of Health recorded almost 300 health care workers as having had training on clinical management of HIV/AIDS.

During the expansion phase, the training team of the National AIDS Control Programme continues to support further building of human capacity to provide care to people living with HIV/AIDS. The implementation guidelines for ARV therapy in Uganda state that, even though ARV drugs may not be directly available or affordable, health providers need to be equipped with regularly updated information that is technically sound and regularly updated. Toward this end, the Ministry of Health seeks to ensure that appropriate training material is developed and that there are training courses for every type of health provider, including physicians, nurses, counsellors, laboratory staff, pharmacists and dispensers (pharmacy technicians).

Training efforts have been relatively successful. By May 2003, six or seven people had been trained in ARV therapy at each of the 11 regional hospitals. This includes two clinicians, two counsellors, two lab technicians, one pharmacist and one dispenser. Twenty-five people have been trained on data entry countrywide. However, more laboratory technicians and counsellors are needed.

New training initiatives developed independently are strengthening the efforts of the government. The Academic Alliance for AIDS Care and Prevention, a global partnership sponsored by Pfizer, is setting up a clinical services programme at Makerere University's teaching hospital and gives training to medical officers. Mildmay International

has also trained health care workers in ARV therapy and counselling, including medical officers, nurses and other types of health care workers. The Ministry of Health is currently updating the records of those who have received and require the training to meet the demand for providing ARV therapy in the country.

The delivery model anticipated in the national plan for scaling ARV treatment up acknowledges that, in the long term, tasks customarily performed by physicians will have to be shared and involve other health care providers, such as clinical officers and nurses who exist in greater numbers, and to enlist community organizations and family members in providing ongoing support to people living with HIV/AIDS.

Accreditation and quality assurance

From the beginning, a defining feature of the Ugandan ARV therapy programme has been that steps were taken to ensure the quality of clinical service delivery. The National Advisory Board developed accreditation criteria for clinical centres that would be authorized to prescribe ARV therapy. There were five accredited centres when the Drug Access Initiative ended, all in Kampala. In the expansion phase, the accreditation of health facilities has continued. Currently, 25 sites have been accredited in Uganda and 23 are providing ARV therapy. Of the 11 regional hospitals, 6 are providing ARV therapy, including Arua, Mbarara, Kabale, Lira, Masaka and Gulu. The minimum criteria for a health facility to be accredited include setting and achieving targets for the comprehensive basic health care services as outlined in the minimum health care package, the presence of basic physical infrastructure (space for HIV counselling and testing, clinical assessment, drug storage and laboratory), minimum numbers of qualified personnel with experience in HIV/AIDS management and the ability to ensure the provision of follow-up care and support for families and communities with people living with HIV/AIDS.

Despite this significant progress, problems remain in ensuring the quality of clinical service delivery, especially in the private sector. The Ministry of Health has started to work with some private providers, and it is hoped that this will change when the draft ARV therapy policy for Uganda (2003) – which foresees that the delivery of ARV therapy in both public and private sectors should be guided by quality standards – is endorsed.

Drug procurement and distribution

There are currently 18 brand-name and 8 generic (in 11 formulations) ARV drugs available in Uganda (Table 3).

Table 3. Antiretroviral drugs available in Uganda

ARV drug	Brand available	Number of Generic formulations available
Zidovudine	Retrovir®	2
Lamivudine	Epivir®	2
Didanosine	Videx®	1
Zalcitabine	Hivid®	
Stavudine	Zerit®	1
Abacavir	Ziagen®	
Efavirenz	Stocrin®	1
Nevirapine	Viramune®	1
Delarviridine	Rescriptor®	
Indinavir	Crixivan®	1
Saquinavir soft gel	Fortovase®	
Saquinavir hard gel	Invirase®	
Nelfinavir	Viracept®	
Ritonavir	Norvir®	
Lopinavir + ritonavir	Kaletra®	
Zidovudine + lamivudine	Combivir®	1
Zidovudine + lamivudine + abacavir	Trizivir®	
Stavudine + lamivudine + nevirapine		1
Hydroxyurea	Hydrea®	

Source: Report on a rapid assessment of access to antiretroviral therapy in Uganda ⁴

ARV agents, just as all other medicines, are required to be registered with the national drug regulatory agency, the National Drug Authority, before they can be imported and used in the country through authorized agents both in the public and private sectors. Under the special authorization process of the National Drug Authority, ARV agents not registered but required are imported for use in Uganda from WHO's list of prequalified suppliers of drugs for HIV/AIDS and other reputable manufacturers.

Most ARV drugs are procured and distributed through the private sector. The two main suppliers are Medical Access Uganda Limited and the Joint Clinical Research Centre.

Medical Access Uganda Limited was established under the Drug Access Initiative as a not-for-profit company to procure drugs at reduced cost from the participating pharmaceutical companies and to sell the products to the centres accredited by the National Advisory Board. In addition, Medical Access Uganda Limited was to monitor the use of the drugs to ensure that they reached their intended recipients and were not diverted to outside markets. Four international pharmaceutical companies contributed towards the operating costs of Medical Access Uganda Limited: Glaxo-Wellcome, Bristol Myers Squibb, Roche Products Ltd and Merck Sharpe and Dohme. Medical Access Uganda Limited is the main supplier of ARV medicines sourced from the research and development-based pharmaceutical industry for the nationally accredited centres in Uganda.

The Joint Clinical Research Centre, a health facility established through collaborative efforts of the Ministry of Health, Makerere University and the Ministry of Defence, was the first treatment centre to participate in the Drug Access Initiative. It started to import generic ARV drugs in 2000. It is now the main supplier of generic ARV drugs in Uganda and services some of the nationally accredited centres and some private practitioners. In addition, the Joint Clinical Research Centre has expanded its

ARV therapy services by providing technical assistance and supplies in regional hospitals.

In addition to these two main suppliers of ARV medicines, the research and development-based pharmaceutical companies continue to distribute their drugs through their local distributors, which mainly target the private market – outside the nationally accredited centres – with their products. In addition to private for-profit distributors, two major not-for-profit procurement organizations procure drugs other than ARV drugs: the Joint Medical Stores and the government-owned National Medical Stores. These two buy and

distribute essential drugs and supplies. Although both have the capacity to procure, store and distribute ARV drugs, they are currently not doing so because of the financial and security risks associated with handling small quantities of relatively expensive drugs.

In the future, it is envisaged that ARV drugs will be procured and stocked in the district hospitals, from which they will be distributed to the health centres they serve. This will require referral centres and regional and district hospitals to strengthen their drug procurement and storage systems. Where drugs are not free of user charges, the centre has to establish a separate account for the purchase of drugs to ensure that funds are not diverted to other hospital expenditure, leading to insufficient drug stocks. With a good drug accountability system, the site coordination team will be able to estimate drug needs so that the appropriate quantity of drugs are bought and stored at the treatment centre.

Drug prices

The research and development-based companies participating in the Drug Access Initiative reduced their prices for a first-line regimen in Uganda from about US\$ 12 000 per year in 1997 to about US\$ 7200 per year in 1999.

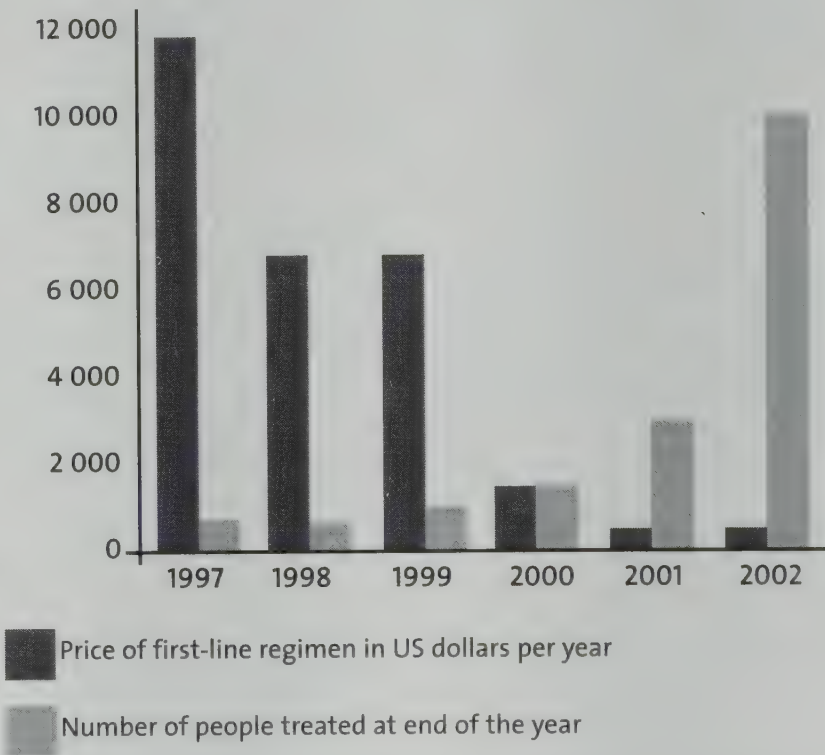
In mid-2000, following the start of importation of generic ARV medicines by the Joint Clinical Research Centre and price reductions by several research and development-based companies as a consequence of the Accelerating Access Initiative, the prices of ARV drugs declined substantially (Fig. 1). Prices fell from US\$ 7200 per year to US\$ 1000 for first-line drug regimens from research and development-based companies and US\$ 480 for a similar first-line generic drug regimen.

As of December 2002, the end-user price of generics was 56 520 Ugandan shillings (about US\$ 31) for a month of treatment using a generic three-drug combination of stavudine, lamivudine and nevirapine (Triomune®). For a combination using zidovudine, lamivudine and efavirenz, the retail price of generics from the same source was 115 200 Ugandan shillings per month (about US\$ 63). Generic drugs introduced by the Joint Clinical Research Centre are increasingly available through a range of private pharmacies.

Although ARV drugs are now available at significantly reduced cost through health facilities accredited by the Ministry of Health, as well as private health facilities, specialized HIV/AIDS care clinics and pharmacies, the government provides no subsidy to the people using them.

As the vast majority of people have no health insurance, many people living with HIV/AIDS continue – despite the reduced cost of the drugs – to have difficulty in covering the costs of their treatment and laboratory tests. This situation might change with financial assistance from development partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the World Bank⁶.

Fig. 1. Trends in the cost of ARV drugs in Uganda, overlaid with the number of people in therapy, 1997–2002



People served

The number of people initially enrolled under the Drug Access Initiative was relatively modest, rising from 450 at baseline in 1997 to 900 people in ARV therapy by 2000. With the establishment of the national programme and significant price reductions of the drugs in 2000, enrolment more than tripled to 3000 by the end of 2001. At the end of 2002, 10 000 people were receiving antiretroviral therapy.

These exponential increases are attributable to reductions in drug prices, the government’s commitment to accrediting more clinical centres and to provide resources to train their staff and, to a lesser extent, action within the private sector (Box 2). The provision of treatment by private and public organizations will be enhanced if the price of ARV agents declines and/or availability increases and all stakeholders, including the community, are sufficiently mobilized.

Box 2. The private sector and access to ARV drugs in Uganda

In 2000, the Bank of Uganda began to offer ARV therapy at subsidized cost to its employees. Today, the Bank's 82 employees in ARV therapy pay 25 % of the drug costs and receive 100 % subsidy for laboratory tests. This initiative has since been followed by other private organizations offering various prevention and treatment packages to their workers. At the African Air Rescue clinic, The Surgery and the International Medical Centre, about 100 people receive subsidies of up to 50 % for ARV therapy from their employers, including the Bata Shoe Company, the New Vision Newspaper, United Nations agencies, Standard Chartered Bank, the Sheraton Hotel and British American Tobacco.

Laboratory monitoring

Three institutions currently provide reference laboratory services in Uganda: the Uganda Virus Research Institute, the Joint Clinical Research Centre and the Case Western Reserve University. The user pays the costs of laboratory tests. In the government health units, HIV testing is free, whereas private facilities charge US\$ 3–5. The AIDS Information Centre, a collaboration between the Ministry of Health and nongovernmental organizations, charges 1000–4000 Uganda shillings (about US\$ 0.5–2) and has more than 20 testing sites in all major centres in Uganda. WHO and the National AIDS Control Programme have an ongoing programme to upgrade, equip and rehabilitate laboratories at the regional hospitals; otherwise CD4 count and viral load tests are done in private facilities or research laboratories. The average cost of a CD4 count test is US\$ 30–50, and viral load testing costs about \$100. Tests are usually performed only when clinically necessary.

The Ministry of Health has made provisions to place a CD4 counter in each of the 11 regional hospitals, to which referrals can be made. Logistical arrangements can be made for the collection and referral of blood and other samples to reference laboratories that perform the tests that cannot be easily done at the collection point.

The draft ARV therapy policy describes the need to accredit laboratories and pharmacies to provide quality assurance for ARV therapy services. It recommends that the Ministry of Health be responsible for developing and implementing this accreditation. Where the laboratory and the pharmacy are part of the same facility at which ARV therapy services are provided, this accreditation can be packaged together.

Guidelines specify that laboratory staff have to be trained on the recent advances in HIV diagnosis and monitoring progression such as CD4 testing, viral load and diagnosis of opportunistic infections. They must also receive training on monitoring special groups such as children and pregnant women.

Clinical results

Weidle et al.³ assessed clinical and laboratory data from three of the five accredited centres participating in the Drug Access Initiative. All users paid for their drugs at negotiated reduced prices. Of the 476 people living with HIV/AIDS assessed, 399 were prescribed ARV drugs at the initial visit, 204 (51 %) receiving triple drug regimens, 189 (47 %) two-drug regimens and six (2 %) monotherapy. Analysis of viral and immune response showed that the viral load of adults living with HIV/AIDS on triple drug regimens declined significantly from baseline versus people on other therapy and more achieved undetectable viral load. At the end of the 2-year pilot period, 52 % of the people originally in therapy were still in care. People in therapy reported up to 88 % adherence. Among the reasons given for nonadherence, 33 % were categorized as financial.

The researchers concluded that, with modest increases in existing resources, an effective system for drug procurement, distribution and accountability could be implemented and maintained. This accomplishment led to an uninterrupted supply of drugs that supported the sustainable management of people in therapy, despite the often-stated financial, logistical and technical impediments to treatment access. Overall, people in therapy reported good adherence, and viral and immune responses were similar to those seen in North America and Europe.

Byakika-Tusiime et al.⁷ investigated the adherence of people in therapy at three treatment centres in Kampala. The people in therapy were recruited from the Joint Clinical Research Centre, Nsambya Hospital and Mildmay International. About one third of the people in therapy reported less than 95 % adherence, and 29 % reported less than 80 % adherence. The factors that were highly associated with nonadherence at less than 95 % adherence were forgetfulness, and the factors associated with less than 80 % adherence were forgetfulness and inaccessibility of drugs. Monthly income was also a factor. The authors concluded that the ability to purchase and secure a stable supply of ARV agents is a great barrier to adherence.

The delivery model for scaling up

Expanding access to ARV therapy in Uganda is being pursued through a phased approach. The pace of expansion will

depend on the financing mechanisms for ARV therapy, the cost of treatment to users, strengthening the health system, the model of service delivery adopted and the involvement of all stakeholders, including the community and development partners. Scaling up is expected to take place in districts with no ARV therapy services and within districts already implementing ARV therapy.

The implementation guidelines for scaling up ARV treatment in Uganda outline a primary care and community home-based care model (Fig. 2) with the ultimate goal of ensuring that ARV therapy services are expanded down to health centre IV level (medical officer in charge) with follow-

up and support extending to health centre levels III to I* (community level). The expansion plan calls for 11 regional hospitals to provide access to ARV therapy by the end of 2003 (currently 6 do). By the end of 2004, 20 districts hospitals will be added to that total. By end of 2005, all hospitals in the country and 20 level IV health centres, and by the end 2006, all level IV health centres will provide ARV therapy. Treatment guidelines that have been drafted are being field-tested. As voluntary counselling and testing is the first point of entry to ARV therapy provision, the Ministry of Health is working to set up voluntary counselling and testing points at all level IV health centres.

Fig. 2. Model of service delivery

Hospital or level IV health centre

- Health centre or outpatient department refers person living with HIV/AIDS to physician
- Assessed or reassessed
 - Counselling and psychosocial support
 - Revised treatment plan
 - Referred back to health centre

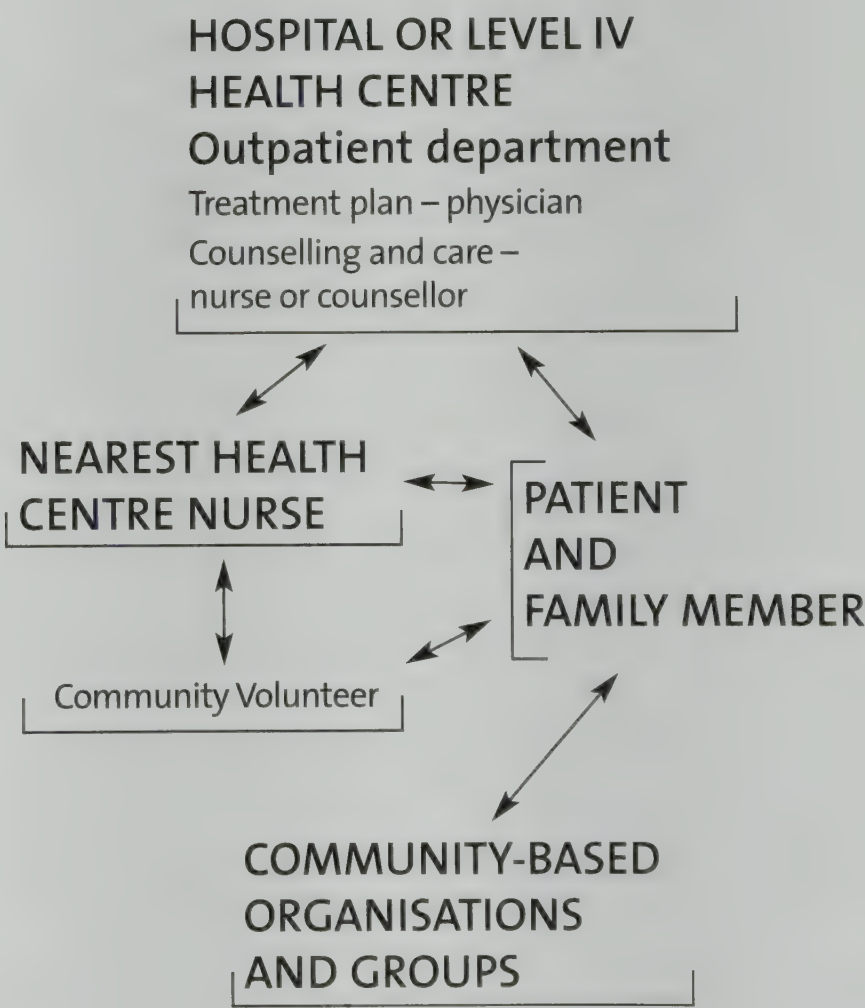
Health centre

- Follow-up of people in therapy
- Supply drugs monthly
 - Check-ups, such as blood pressure
 - Ongoing counselling and encouragement
 - Identify problems
 - Refer to hospital outpatient department

Community

- Motivate
- Educate person in therapy and family
- An approach using directly observed therapy for tuberculosis
- Inform health centre of problems
- Link with community organizations and groups for social and material support

Source : Implementation Guidelines for ART in Uganda ⁴



* I: community health worker, not facility-based; II: physical structure, nurse in charge; III: level II plus a maternity delivery service, midwife in charge.

This model is proposed to extend assistance to the most remotely located people living with HIV/AIDS. At the most basic level, support will be provided to people living with HIV/AIDS whether or not they are on ARV therapy, focusing on diagnosing and managing opportunistic infections. Community health workers will be expected to identify clients and refer to more comprehensive services at higher health care service levels. Services will be linked to communities through home-based care, which will include palliative care and management of pain. People living with HIV/AIDS can be referred when needed to the next appropriate level by key players in this model such as nongovernmental community-based organizations and volunteers, community health workers, family members and friends.

Community involvement

Involvement of community members and people living with HIV/AIDS in the National Advisory Board of the Drug Access Initiative was an important factor in the success of the pilot programme. As ARV therapy is scaled up in Uganda, the Ministry of Health envisages greater involvement of community health workers and organizations in supporting adherence and individual follow-up (Box 3).

Box 3. The Uganda Cares programme

The Uganda Cares programme in Masaka, supported by the Ministry of Health, the Government of Uganda, the Uganda Business Coalition and the AIDS Healthcare Foundation, is an example of an integrated community-based and -driven ARV therapy centre operated by a consortium of partners. Uganda Cares offers three large community-based organizations in Masaka a quota each on the number of people living with HIV/AIDS they could identify to treat with ARV drugs through a system of referral from community-based organizations. It trained members of community-based organizations, district leaders, local council heads and people living with HIV/AIDS on adherence and support and on issues related to follow-up. In February 2003, Uganda Cares, which employs one physician and one nurse, had 102 people (including 20 children) on ARV therapy in a family-based programme based on preventing the mother-to-child transmission of HIV within the community (the MTCT-Plus model), with a 96% adherence rate so far. The eligibility criteria were a CD4 count of less than $150/\text{mm}^3$, having a demonstrable family unit, absence of a history of alcohol or drug abuse and absence of psychotic behavior. In working with Kitovu Mobile, a faith-based community-based organization, Uganda Cares also learned that, beyond treatment support, returning people living with HIV/AIDS to good health also requires support in returning to activities that give them a sense of achievement and purpose. Kitovu Mobile has helped some people start small businesses such as goat-rearing with very positive results.

Information, education and communication

Under the Drug Access Initiative, activities were undertaken to educate and communicate to the public the availability of HIV treatment, how it works, its effectiveness and where to get further advice on treatment. A leaflet endorsed by both the Government of Uganda and UNAIDS was distributed to the public during this early phase.

In the expansion phase, public awareness of ARV therapy has largely resulted from personally knowing individuals who are in therapy. Consequently, awareness is still fairly low. While government efforts have been complemented by those of NGOs, community-based organizations and others, more efforts in providing information and advocacy on comprehensive care and support are needed. The public also needs information on the availability of care and support services.

Funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria and other sources should help to remedy this situation with campaigns to inform, educate and communicate to a larger audience. Materials that are proposed for development include booklets for people living with HIV/AIDS, a booklet on ARV therapy, a guide on dispensing ARV agents, information leaflets for the public and a compendium of ARV drugs with details on dosage forms, pharmacokinetics and pharmacodynamics, metabolism, side effects, drug interactions and adverse reactions.

New partnerships for scaling up

Uganda's successful early experience in providing ARV therapy in a resource-limited setting has contributed to the approval of Uganda's proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The two-year grant of over US\$ 36 million will assist in financing a range of National Strategic Framework activities, including US\$ 9 million earmarked for procuring ARV drugs. The World Bank Multi-Country HIV/AIDS Program for the Africa Region is providing an additional US\$ 3 million.

The Academic Alliance for AIDS Care, supported by Pfizer, is building an Infectious Diseases Institute on the campus of Makerere University. This will educate and train African physicians and health care providers on HIV care and prevention and provide state-of-the art diagnostic laboratory facilities for HIV monitoring. The Alliance also plans to contribute to the cost of ARV therapy for users.

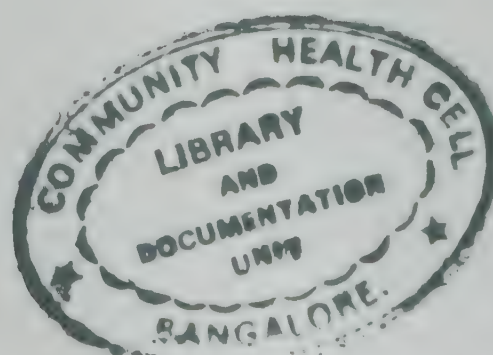
The increasingly available funds from third parties will help to ensure that government expenditure on HIV prevention and other public health priorities will not be negatively affected by scaling up access to ARV therapy.

Conclusion

Uganda has created a programme on access to ARV therapy that keeps expanding largely based on Ugandan resources. Key to its success has been the will to act and not wait for external assistance. The success of its pilot programme has now mobilized additional technical and financial resources to scale up access to ARV therapy and to integrate it in a comprehensive health sector response to the epidemic. Drawbacks of the current programme remain its insufficient coverage, difficulties finding the people that can ensure the care of people living with HIV/AIDS and the fact that the cost of ARV therapy is still out of the financial reach of many people. The expansion of the ARV therapy programme, which will benefit from the input of the Global Fund to Fight AIDS, Tuberculosis and Malaria, will address these challenges and will ensure a more efficient and ethical use of ARV drugs to consolidate Uganda's achievements.

References

- ¹ Ochola D et al. *Uganda Ministry of Health – UNAIDS HIV/AIDS Drug Access Initiative. Preliminary report*. Geneva, UNAIDS, March 2000 (http://www.unaids.org/publications/documents/care/UNAIDS_DAI/uganda_drug_access_initiative.doc, accessed 30 May 2003).
- ² *The National Strategic Framework for Expansion of HIV/AIDS Care & Support in Uganda, 2001/2–2005/6*. Kampala, Ministry of Health, February 2002.
- ³ Weidle P et al. Assessment of a pilot antiretroviral drug therapy programme in Uganda: patients' response, survival and drug resistance. *The Lancet*, 2002, 360: 36–40.
- ⁴ *Report on a rapid assessment of access to antiretroviral therapy in Uganda*. Geneva, World Health Organization (draft), Ministry of Health, Uganda and World Health Organization, Uganda office.
- ⁵ *National ARV treatment and care guidelines for adults and children*. Draft 9. Kampala, Ministry of Health, March 2003.
- ⁶ *Fact sheet: Uganda*. Geneva, Global Fund to Fight AIDS, Tuberculosis and Malaria, 2003 (<http://www.globalfundatm.org/journalists/fsheets/uganda.html>, accessed 30 May 2003).
- ⁷ Byakika-Tusiime J et al. *Ability to purchase and secure stable therapy are significant predictors of non-adherence to antiretroviral therapy in Kampala, Uganda*. 10th Conference on Retroviruses and Opportunistic Infections, Boston, MA, USA, 10–14 February 2003 (abstract 170; <http://www.retroconference.org/2003/Abstract/Abstract.aspx?AbstractID=1808>, accessed 30 May 2003).
- ⁸ *Implementation Guidelines for ART in Uganda*, Ministry of Health, Uganda (draft, May 2003).



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